



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Foot Care for Patients With Diabetes and Additional Risk Factors for Amputation

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections assessed whether patients with diabetes mellitus and additional risk factors for lower extremity amputation received annual foot care in accordance with Veterans Health Administration (VHA) requirements.

The study population consisted of patients with a diagnosis of diabetes mellitus and one or more of the following risk factors for amputation during July 1, 2009–February 28, 2010: peripheral vascular disease, peripheral neuropathy, and Charcot joint disease with foot deformity. We used a two-stage approach to evaluate the annual rate of patient encounters with VA or fee basis foot care specialists. We first examined administrative data for evidence of specialized foot care and then conducted a focused electronic health record review of a randomly selected sample of patients for whom there was no evidence of annual care in administrative data.

We estimated the VHA compliance rate for annual foot care in this population at increased risk to be 66.2 percent, and we are 95 percent confident that the actual compliance rate is between 64.95 and 67.49 percent.

We recommended that the Under Secretary for Health implement a plan to ensure compliance with VHA's requirement that patients who are at moderate or high risk for amputation be examined by a foot care specialist at least once each year.

The Under Secretary for Health concurred with the findings and recommendations. See Appendix B (pages 8-9) for the full text of his comments.

We will follow up on the corrective actions until all recommendations have been fully implemented.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health

SUBJECT: Healthcare Inspection – Foot Care for Patients With Diabetes and Additional Risk Factors for Amputation

Purpose

To determine if patients with diabetes and additional risk factors for lower extremity (LE) amputation received care in accordance with Veterans Health Administration (VHA) requirements.

Background

More than 8 percent of Americans carry the diagnosis of diabetes mellitus¹ and the rate exceeds 20 percent among patients treated at Veterans Health Administration (VHA) hospitals and clinics.² Persistent elevated blood glucose levels lead to vascular and neurologic disease, and diabetes is the leading cause of nontraumatic LE amputation in the United States.³ Preventive measures, such as instructing patients on foot care and proactive medical assessment and treatment, reduce the likelihood that foot problems progress to amputation. Programs that include regular examinations and patient education may prevent up to 85 percent of diabetes-related amputations.⁴

To prevent and treat LE complications that can lead to amputation in these patients, VHA established the Preservation-Amputation Care and Treatment Program in 1993.⁵ Recently re-designated Prevention of Amputation in Veterans Everywhere (PAVE), the program provides for the identification of at-risk individuals and describes four levels of foot risk – normal, low, moderate, and high – and specifies actions to be taken for each level of risk (Appendix A, Table 1). Many of these actions are the responsibility of

¹ Centers for Disease Control and Prevention. 2011 National Diabetes Fact Sheet. <http://www.cdc.gov/diabetes/pubs/estimates11.htm>. Accessed September 10, 2012.

² Kirsh S, Hein M, Pogach L, et al. Improving outpatient diabetes care. *Am J Med Qual*. 2012;27:233-40.

³ Ismail-Beigi F. Glycemic management of type 2 diabetes mellitus. *N Engl J Med*. 2012;366:1319-27.

⁴ Diabetes Prevention and Control, The U.S. Department of Health and Human Services' National Diabetes Education Program. <http://www.diabetesatwork.org/GettingStarted/DiabetesControl.cfm>, accessed July 27, 2012.

⁵ VHA Directive 2012-020. Prevention of Amputation in Veterans Everywhere (PAVE) Program. August 20, 2012.

primary care providers, with augmentation by referrals to podiatrists, vascular surgeons, and other health care professionals trained to provide specialized foot care.

VHA defines moderate risk patients as those having loss of sensation along with absent or weakly palpable pulses, a foot deformity, or a foot infection. Patients at high-risk are those meeting moderate risk criteria and with any of the following additional diagnoses:

- Ulceration, osteomyelitis (bone infection), or prior amputation
- Severe peripheral vascular disease (PVD, a condition of narrowed blood vessels that restrict blood flow in the legs and feet)
- Charcot's joint disease (a foot disease associated with neuropathy that results in destruction of joints) with foot deformity
- End-stage renal disease

Scope and Methodology

The study population included patients who had inpatient or outpatient encounters with VHA or fee basis providers during July 1, 2009–February 28, 2010, and who met both of the following criteria: 1) an encounter associated with the diagnosis of diabetes mellitus and, 2) an encounter associated with any of the following additional risk factors for LE amputation: PVD, peripheral neuropathy (PN), or Charcot's joint disease (Appendix A, Table 2). Data were obtained from VHA's National Patient Care database, Patient Treatment File, and Fee Inpatient and Outpatient Payment files.

We considered a patient to have received annual foot care if there was evidence of a qualifying foot care encounter in the 13 months following the patient's index date. The index date was the first day during the review period on which the patient satisfied both inclusion criteria. Qualifying foot care by VHA or non-VHA providers was considered to be any of the following: a detailed foot examination, LE vascular testing, evaluation or fitting of an orthotic device⁶ or footwear, and a podiatry clinic visit (Appendix A, Table 3).

We used a two-stage approach to evaluate the annual rate of patient encounters with VA or fee basis foot care specialists. We first examined administrative data for evidence of specialized foot care and then conducted a focused electronic health record (EHR) review of a randomly selected sample of patients for whom there was no evidence of annual care in administrative data. To optimize the efficiency of EHR review, we examined only those records with no administrative data evidence of foot care through March 31, 2011 (14-30 months from index dates).

⁶ An orthotic device is placed in a shoe to accommodate foot deformities, compensate for soft tissue atrophy, and evenly distribute foot pressures.

Assuming a compliance rate of 60 percent based on a pilot chart review, and desired margin of error of 4 percentage points, we randomly selected 623 patients for EHR review. Reviewers used a standardized protocol, including key word text searches, to confirm the absence of qualifying foot care, and to exclude patients with any of the following:

- No evidence of diabetes or risk factors for amputation
- Death within 13 months of the index date
- Double LE amputation
- Hospice or end of life care

This review did not evaluate the appropriateness, accuracy, or quality of any encounters or encounter codes.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Results

We found through administrative data that 82,305 patients had a diagnosis of diabetes and one or more risk factors for LE amputation (peripheral vascular disease, peripheral neuropathy, Charcot joint disease) during July 1, 2009–February 28, 2010. The mean age of these patients was 69.6 years (median, 68.0; range, 24-101) and 98.4 percent were male. In the second stage of the evaluation, 623 patients who had no database evidence of foot care were randomly selected for EHR review. See Figure.

EHR review revealed that for 105 patients (16.8 percent) there was EHR evidence of qualifying foot care encounters within 13 months of their index dates, including evidence of non-VA care discovered in VHA provider notes. Forty-five patients had an examination by a foot care specialist, 37 patients had a specialized LE vascular examination, and 48 patients had footwear or an orthotic device issued.⁷

Reviewers also found that 65 patients (10.4 percent) should not have been included in the study population. Forty patients died before the end of the study period, 12 did not have a diagnosis of diabetes, 10 had double lower extremity amputations, and 3 were enrolled in hospice or end of life care.

⁷ Some patients had more than one type of qualifying foot care encounter.

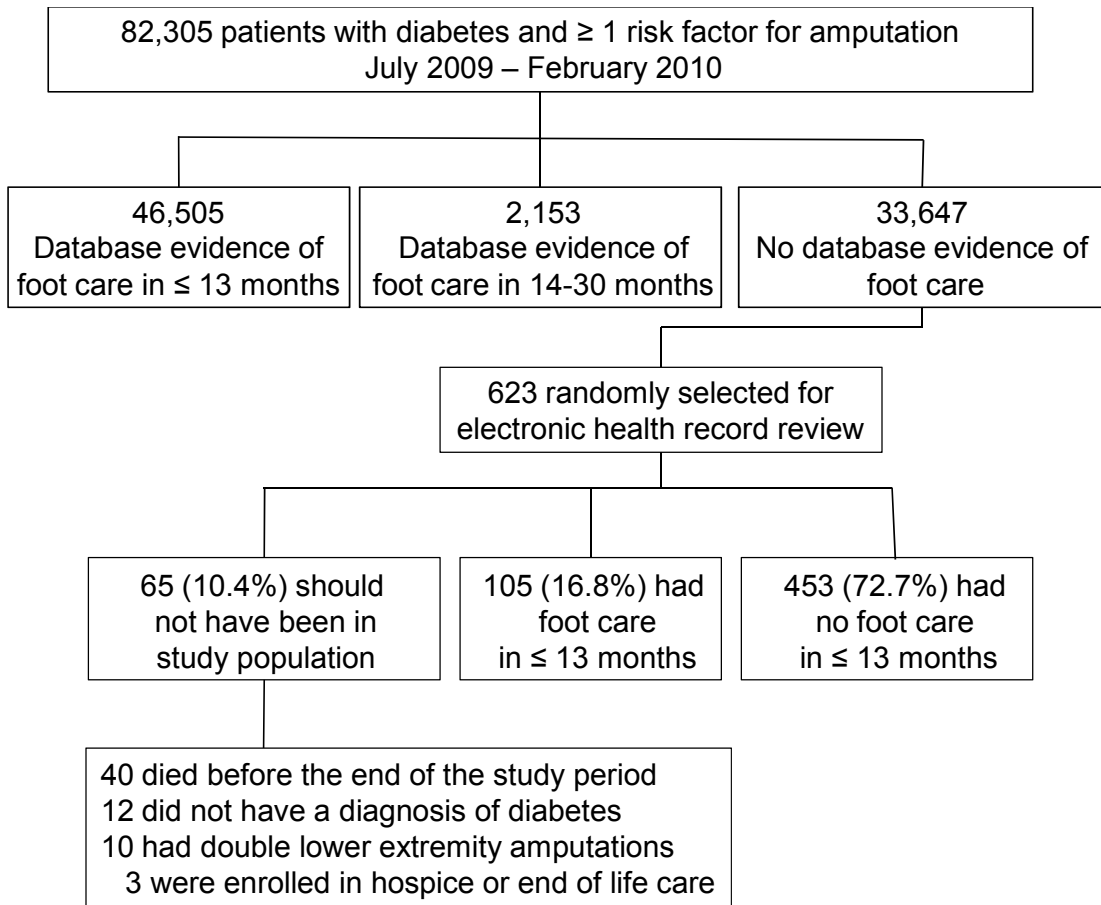


Figure. Review Flow

We estimated VHA compliance rate was 66.2 percent (95 percent confidence interval, 64.95 – 67.49 percent), adjusting for excluded patients and qualifying encounters found by EHR review.

Conclusion

We found that approximately one-third of patients with diabetes who were at increased risk for amputation had no documentation of required foot care.

Recommendation

We recommended that the Under Secretary for Health implement a plan to ensure compliance with VHA's requirement that patients who are at moderate or high risk for amputation be examined by a foot care specialist at least once each year.

Comments

The Under Secretary for Health agreed with our findings and recommendations. The implementation plans are acceptable, and we will follow up until all actions are completed.

A handwritten signature in black ink, reading "John D. Daigh, Jr., M.D." in a cursive script.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Tables

Table 1: PAVE Program Referral Strategy for Moderate and High Levels of Risk for Amputation

Level 2, Moderate-Risk		
Demonstrates one or both:	Patients need to receive:	Referral strategy:
Sensory loss	Foot care education	Appropriate care for systemic conditions
Diminished foot circulation, deformity, or minor infection	Annual screening	Non-invasive vascular laboratory testing
	Preventive foot care	Referral to vascular surgery if diminished circulation
	Therapeutic footwear and orthoses	Referral to podiatry or foot care specialist for examination and care
Level 3, High-Risk		
Demonstrates one or both:	Patients need to receive:	Referral strategy:
PN with sensory loss	Foot care education	Appropriate care for systemic conditions
Diminished foot circulation, deformity, or minor infection	Preventive foot care	Non-invasive vascular laboratory testing
Or any by itself:		
Prior ulceration, osteomyelitis, or history of amputation	Extra depth footwear with soft molded inserts	Referral to vascular surgery if diminished circulation
Severe PVD	More frequent clinic visits	Referral to podiatry or foot care specialist for examination and care
Charcot's joint disease with foot deformity	May require custom molded shoes and braces	Immediate referral if an acute condition is present, and evaluation for secondary complications and referral.
End-Stage Renal Disease		

PN = peripheral neuropathy, PVD = peripheral vascular disease

Table 2: Co-morbidities

Diagnoses with one or more of the following International Classification of Diseases, Ninth Revision (ICD-9) codes:	
DM	250.0-250.9
PN	356.0-356.9
PVD	440.20-440.24; 440.4; 443.0; 443.8; 443.81; 443.9
Charcot	713.5

DM = Diabetes Mellitus, PVD = peripheral vascular disease, PN = peripheral neuropathy, Charcot = Charcot joint disease

Table 3: Codes Considered as Evidence of Foot Care

ICD-9 Codes & Category of Foot Care		CPT Codes & Category of Foot Care	
0003	Vascular Procedure (ICD-9)	G0245	Foot Exam
3829	Vascular Procedure (ICD-9)	G0246	Foot Exam
8877	Vascular Procedure (ICD-9)	G0247	Foot Exam
9302	Orthotic/Insert (ICD-9)	2028F	Foot Exam
9323	Orthotic/Insert (ICD-9)	93922	Vascular Procedure (CPT)
9324	Orthotic/Insert (ICD-9)	93923	Vascular Procedure (CPT)
		93924	Vascular Procedure (CPT)
HCPCS Codes & Category of Foot Care			
A5500	Orthotic/Insert	L3040	Orthotic/Insert
A5501	Orthotic/Insert	L3050	Orthotic/Insert
A5503	Orthotic/Insert	L3060	Orthotic/Insert
A5504	Orthotic/Insert	L3070	Orthotic/Insert
A5505	Orthotic/Insert	L3080	Orthotic/Insert
A5506	Orthotic/Insert	L3090	Orthotic/Insert
A5507	Orthotic/Insert	L3215	Orthotic/Insert
A5508	Orthotic/Insert	L3216	Orthotic/Insert
A5510	Orthotic/Insert	L3217	Orthotic/Insert
A5512	Orthotic/Insert	L3219	Orthotic/Insert
A5513	Orthotic/Insert	L3222	Orthotic/Insert
L3000	Orthotic/Insert	L3230	Orthotic/Insert
L3002	Orthotic/Insert	L3252	Orthotic/Insert
L3010	Orthotic/Insert	L3253	Orthotic/Insert
L3020	Orthotic/Insert		
Clinic Stop Codes (primary or secondary)		411	Podiatry Clinic

CPT = Current Procedural Terminology, HCPCS = Healthcare Common Procedure Coding System,
ICD-9 = International Classification of Diseases, Ninth Revision

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: November 16, 2012

From: Under Secretary for Health (10)

Subject: Healthcare Inspection – Foot Care for Patients with Diabetes Mellitus and Risk for Amputation

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report and concur with the report's recommendation.
2. Thank you for the opportunity to review the draft report. Attached is the complete corrective action plan for the report's recommendations. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10AR) at (202) 461-7014.

(original signed by:)
Robert A. Petzel, M.D.

Attachment

Under Secretary for Health Comments to Office of Inspector General's Report

The following comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendation

Recommendation: We recommended that the Under Secretary for Health implement a plan to ensure compliance with VHA's requirement that patients who are at moderate or high risk risk for amputation be examined by a foot care specialist at least once each year.

VHA Response

Concur

The Deputy Under Secretary for Health for Operations and Management will issue a letter reinforcing VHA Directive 2012-020, Prevention of Amputation in Veterans Everywhere (PAVE), highlighting the need to ensure that moderate and high risk patients are seen by Veterans Health Administration (VHA) foot care specialists or document that the patients are being seen in the private sector. The current annual foot check requirement can be used for this purpose.

Status: In process To be completed NLT March 31, 2013

VHA will modify the annual PAVE report to document moderate and high risk patients who receive specialty foot care visits either within VHA or the private sector based on annual chart review of 30 randomly selected charts of high and moderate risk patients.

Status: In process To be completed: The report will be modified by June 2013 and will be due in December 2013 as per VHA Directive 2012-020

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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Acknowledgments	Bruce Barnes Don Braman, RN Jennifer Christensen, DPM Lin Clegg, PhD Jarvis Yu, MS Myra Conway, RN Melanie Oppat, MEd, LDN Katharine Foster, RN Cynthia Gallegos, Program Support Assistant Donna Giroux, RN Kathy Gudgell, RN, JD Jerome E. Herbers, Jr., MD Nelson Miranda, LCSW Victor Rhee, MHS Sonia Whig, MS, LDN
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